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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,396	08/06/2001	Wolff M. Kirsch	LOMAU.140A	6247

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NATIONAL INSTITUTES OF HEALTH
OFFICE OF TECHNOLOGY TRANSFER
6011 EXECUTIVE BLVD SUITE 325
ROCKVILLE, MD 20852-3804

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,396	KIRSCH ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-9 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claims 1-6 and 10-19 have been cancelled, claims 7 and 9 have been amended and claim 20 has been added as requested in the amendment of Paper No. 22, filed on June 12, 2003. Claims 7-9 and 20 are pending in the instant application.

Claims 7-9 and 20 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on June 12, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. Claims 7-9, as amended, and claim 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record in section 4 of Paper No. 17.

Claims 7-9, as amended are directed to a method of identifying a subject in need of treatment or prevention of Alzheimer's disease, Parkinson's disease or MCI by determining the presence a probe that interacts with a wild type or mutant IRP-2 protein in the amount significantly greater than identified in a control sample, wherein the sample comprises peripheral

blood cells. Claim 20 allows for the identification of a subject in need of treatment or prevention of Alzheimer's disease, Parkinson's disease or MCI based on the ability of a probe to interact with IRP-2. Applicant submits Declaration under 37 CFR 1.132 to support the claimed invention.

The Declaration of Kirsch under 37 CFR 1.132 filed June 12, 2003 is insufficient to overcome the rejection of claims 7-9 and 20 for the following reasons. The Declaration provides an immunocytochemistry microphotograph, which shows that "lymphocytes stained with IRP-2 antibodies produce a clearly different pattern for Alzheimer's disease patients as compared to controls" (see page 2, section 5 of the Declaration and Exhibit B). First, it appears that the presented photograph is obtained from one patient, therefore, it cannot be concluded that it represents "Alzheimer's disease patients as compared to controls" because it includes only one single example. Second, the photograph clearly could not provide any support for the claimed quantitative method (see claim 7, which recites detection of the significantly different amount of probe). Furthermore, as it is clearly demonstrated in Exhibit D, the patient, from which the sample was collected, was diagnosed with short term memory loss and not Alzheimer's disease. It is well known in the art that the clear diagnosis of Alzheimer's disease can only be made based on postmortem brain tissue analysis (see Motter et al., and Clark et al., for example). Thus, the Declaration of Kirsch, as well as the instant specification, as filed, fail to provide any evidence or sound scientific reasoning to allow a conclusion that determination of the presence of IRP-2 in any amount in a sample of peripheral blood cells would lead to identifying a subject in need of treatment of Alzheimer's disease. One skilled in the art would have to resort to significant amount of undue experimentation to discover how to estimate what amount of a probe, as recited in claim 7, would correlate to the diagnosis of Alzheimer's disease.

The statement in section 7 of the Declaration of Kirsch regarding possible association of IRP-2 and Parkinson's disease have been fully considered but is found to be unsubstantiated either by factual data or by any evidential support in the art.

Further, it is also clear that the instant specification fails to demonstrate a clear nexus between Alzheimer's disease, Parkinson's disease and MCI, which allows for the common diagnosis. While it is not necessary that Applicant understands or discloses the mechanism by which the invention functions, in this case, in the absence of such an understanding, no generalization can be made of the recited conditions unless apparent evidence is submitted to support such statement.

Finally, there is no information presented in the instant specification that would allow one to identify subjects that are in need of "prevention of Alzheimer's disease, Parkinson's disease or MCI", emphasis added. It appears that such subjects would reasonably include most of the general population and the instant specification does not provide any guidance how to specifically distinguish and discriminate those in need of prevention from those that are not.

Thus, Applicant's invention is predicated on the finding that mutations in the IRP-2 gene perturb iron homeostasis. Applicant further extrapolates this result into a method for diagnosis of Alzheimer's disease, Parkinson's disease or MCI. Accordingly, it would appear that Applicant provides a single finding (the finding), and then presents an invitation to experiment to determine if and how a pattern of distribution of a wild type or a mutant type of IRP-2 in Alzheimer's disease, Parkinson's disease or MCI differs from a normal pattern.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method without first making a substantial inventive contribution.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7-9 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 7 is vague and indefinite for recitation of "a wild type or mutant [...] IRP-2 protein (SEQ ID NO: 18). As evidenced by the text on page 8, line 20, for example, SEQ ID NO: 18 represents a wild type IRP-2 polypeptide. It is not clear how a wild type and a mutant type could have the same amino acid sequence.

8. Claim 7 is further indefinite for recitation of "MCI". A full name of the acronym must be presented at its first appearance in the claims.

9. Claim 20 is vague and ambiguous because it is not clear what determines the identification. Is it "the determination whether the probe interacts with the polynucleotide or protein in the biological samples identifies the subject", emphasis added? Or is it the ability of the probe to interact or not with the polynucleotide or protein?

10. Claim 20 recites the limitation "the polynucleotide" in claim 7. There is insufficient antecedent basis for this limitation in the claim.

11. Claims 8-9 are indefinite for being dependent from indefinite claim.

Conclusion

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
September 2, 2003

JOHN ULM
PRIMARY EXAMINER
GROUP 1800